

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/634,477
	Filing Date	August 4, 2003
	First Named Inventor	Lehmann et al.
	Art Unit	
	Examiner Name	
Total Number of Pages in This Submission	Attorney Docket Number	21368 US

ENCLOSURES (Check all that apply)		
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<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	-References B1-B15 and B20, and C1-C2	
<b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>		
Firm or Individual	Patricia S. Rocha-Tramaloni	
Signature		
Date	October 27, 2003	

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313 on this date <u>October 27, 2003</u>			
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Serial No. 10/634,477  
Filed: August 4, 2003

The Examiner's attention is particularly directed to

- a) P. Lehmann, M. Volkmann, J. Lotz, A. Baldauf, R. Roeddiger, poster presented at the AACC/CSCC, Annual Meeting, July 29 - August 2, 2001, Chicago Illinois, and
- b) WO 98/41226 (Case Docket 20356), both enclosed.

Since the Information Disclosure Statement is submitted before the mailing of the first Office Action on the merits or within three months of the filing date for the above application, no fee is due.

Respectfully submitted,



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Enclosures

135386



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Inventor(s): Lehmann, et al.

Serial No. 10/634,477, filed August 4, 2003  
(Ref. No. 21368 US)

For: **TREATMENT OF DISTURBANCES OF IRON DISTRIBUTION**

**INFORMATION DISCLOSURE STATEMENT**

Nutley, New Jersey 07110  
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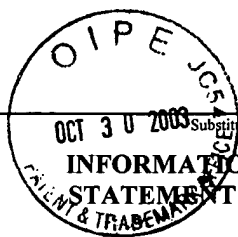
Commissioner for Patents  
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Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, applicants respectfully direct the Examiner's attention to the documents listed on enclosed Form PTO-1449.

Documents B1-B15 and B20, and C1-C2 listed on Form PTO-1449 are enclosed. Document B14 is not in the English language and is abstracted in Document C2. Copies of documents A1 to A13 are not enclosed as they are U.S. patents. Copies of documents A14-A19, B16-B19 and C3-C18 are not being submitted as they are made of reference in related U.S. application Serial No. 10/047,749, filed October 23, 2001, pending.

Consideration of all the documents cited on Form PTO-1449 is requested.



Substitution for form 1449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use several sheets if necessary)			<b>Complete if Known</b>	
			Application Number	10/634,477
			Filing Date	August 4, 2003
			First Name Inventor	Lehmann, et al.
Sheet	1	of 3	Attorney Docket Number	21368 US

### U.S. PATENT DOCUMENTS

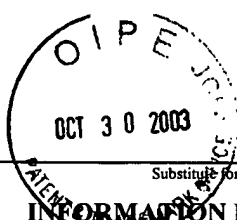
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	A1	5,733,761		Treco et al.	03/31/1998
	A2	5,641,670		Treco et al.	06/24/1997
	A3	5,733,746		Treco et al.	03/31/1998
	A4	5,994,127		Selden et al.	11/30/1999
	A5	6,528,313		Le Mouellic et al.	03/04/2003
	A6	5,981,214		Skoultchi	11/09/1999
	A7	5,272,071		Chappel	12/21/1993
	A8	5,359,030		Ekwuribe	10/25/1994
	A9	5,681,811		Ekwuribe	10/28/1997
	A10	4,179,337		Davis et al.	12/18/1979
	A11	5,324,650		Obzansky et al.	06/28/1994
	A12	6,583,272		Bailon	06/24/2003
	A13	5,672,662		Harris et al.	09/30/1997
	A14	5,541,158		Vance et al.	07/30/1996
	A15	4,745,099		Akamatsu et al.	05/17/1988
	A16	6,333,306		Lehmann et al.	12/25/2001
	A17	US 2002/0160956 A1		Lehmann et al.	10/2002
	A18	5,376,632		Konings et al.	12/27/1994
	A19	6,372,715		Kaltwasser et al.	04/16/2002

### FOREIGN PATENT DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	B1	EP	640619		Amgen Inc.	03/01/1995	
	B2	WO	01/02017		F.Hoffmann-La Roche AG	01/11/2001	
	B3	EP	1064951		F.Hoffmann-La Roche AG	01/03/2001	
	B4	EP	539167		Ortho Pharmaceutical Corp.	04/28/1993	
	B5	EP	605963		Ortho Pharmaceutical Corp.	07/13/1994	
	B6	WO	93/25212		Amgen Inc.	12/23/1993	
	B7	WO	94/20069		Amgen Inc.	09/15/1994	
	B8	WO	95/11924		Enzon, Inc.	05/04/1995	
	B9	EP	584876		Sterling Winthrop Inc.	03/02/1994	
	B10	WO	92/16555		Enzon, Inc.	10/01/1992	
	B11	WO	94/28024		Enzon, Inc.	12/08/1994	
	B12	WO	97/04796		Protein Delivery Inc.	02/13/1997	
	B13	WO	98/32466		Polymasc Pharmaceutical PLC	07/30/1998	

<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup>Unique citation designation number. <sup>3</sup>See attached Kinds of U.S. Patent Documents. <sup>4</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation or abstract is attached.



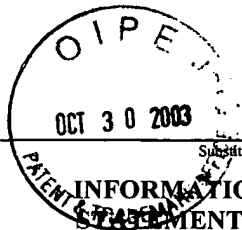
Substituted for form 1449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use several sheets if necessary)				<b>Complete if Known</b>	
				Application Number	10/634,477
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				First Name Inventor	Lehmann, et al.
Sheet	2	of	3	Attorney Docket Number	21368 US

#### FOREIGN PATENT DOCUMENTS

	B14	DE 3924705	Boehringer Mannheim GmbH	01/31/1991	
	B15	WO 01/87329	F.Hoffmann-La Roche AG	11/22/2001	
	B16	EP 0411678	Genetics Institute Inc.	02/06/1991	
	B17	EP 0205564	Genetics Institute Inc.	12/30/1986	
	B18	EP 0286439	Ortho Pharmaceutical Copr.	10/12/1988	
	B19	WO 97/09996	Boehringer Mannheim GmbH	03/20/1997	
	B20	WO 98/41226	Boehringer Mannheim GmbH	09/24/1998	

#### NON PATENT LITERATURE DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	C1	P. Lehmann, M. Volkmann, J. Lotz, A. Baldauf, R. Roeddiger, poster presented at the AACC/CSCC, Annual Meeting, July 29 - August 2, 2001, Chicago Illinois	
	C2	Abstract corresponding to DE 3924705	
	C3	Grützmacher P., et al., <i>Clinical Nephrology</i> , vol. 38, pp 92-97, 1992	
	C4	Wick, M.; Pinggera, W.; Lehmann, P., <i>Eisenstoffwechsel Diagnostik und Therapie der Anämien</i> , 3 <sup>rd</sup> edition, Springer, Wien, NY, pp 5-14, 38-55, 65-80, 94-98, Sept. 1996	
	C5	Sunder-Plassmann G., et al., <i>Journal of the American Society of Nephrology</i> , 5, (3), pp 478 (1994).	
	C6	Gasche C., et al., <i>Dig. Dis. Sci.</i> , 39, (9) pp 1930-4 (1994).	
	C7	Sunder-Plassmann G., et al., <i>Nephrology Dialysis Transplantation</i> , 10, (11), pp 2070-2076 (1995).	
	C8	Mercuriali F. et al., <i>Erythropoiesis: New Dimensions in the Treatment of Anaemia</i> , 6/3, pp 67-76, (1995).	
	C9	Sunder-Plassmann G., et al., <i>Nephrology Dialysis Transplantation</i> , 11, (9), pp 1797-1802, (1996).	
	C10	Taylor J. E., et al., <i>Nephrology Dialysis Transplantation</i> , 11, (6), pp 1079-1083, (1996).	
	C11	Breymann, et al., <i>Eur. J. Clin. Invest.</i> , pp 123-30.	
	C12	Goodnough, et al., <i>Haematology</i> , 1(2), pp 163-166.	
	C13	MacDougall (1994) Monitoring of Iron Status & Iron Supplementation in Patients Treated with Erythropoietin. <i>Current Opinion in Nephrology &amp; Hypertension</i> 3(6) pgs. 620-625	
	C14	Taylor et al. (1996) Regular low-dose Intravenous Iron Therapy Improves Response to Erythropoietin in Haemodialysis Patients. <i>Nephrology, Dialysis, &amp; Transplantation</i> 11(6) pgs. 1079-1083	
	C15	Means, Jr. (1995) Erythropoietin in the Treatment of Anemia in Chronic Infectious, Inflammatory, & Malignant Diseases. <i>Current Opinion in Hematology</i> 2(3) pgs. 210-213	



<div>Substitute for form 1449A/PTO</div> <div><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></div> <div>(Use several sheets if necessary)</div>				<b>Complete if Known</b>	
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Sheet	3	of	3	Attorney Docket Number	21368 US

**NON PATENT LITERATURE DOCUMENTS**

	C16	Adamson (1996) Erythropoietin, Iron Metabolism, & Red Blood Cell Production. <i>Seminars In Hematology</i> 33(2) pgs. 5-9	
	C17	Mercuriali & Inghilleri (1995) Iron Administration to Optimise the Effect of r-HuEPO in the Surgical Setting. Erythropoiesis: <i>New Dimensions in the Treatment of Anemia</i> 6(3) pgs. 67-76	
	C18	Pincus et al. (August, 1990) Multicultural Study of Recombinant Human Erythropoietin in Correction of Anemia in Rheumatoid Arthritis. <i>The American Journal of Medicine</i> 89(2) pgs. 161-168.	
Examiner Signature			DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation or abstract is attached.

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